REMARKS

Reexamination and reconsideration of this application is respectfully requested in light of the foregoing amendments to claims 12 and 13 and the following remarks.

Claims 1-53 are pending in this application. No claims have been canceled and no new claims have been added. Claims 1-11 and 14-53 have been withdrawn from consideration due to a restriction requirement. Applicant notes the Examiner's reference to the current Office policy regarding searching of one protein sequence and making the restriction final. Claims 12 and 13 have been amended. Support for the amendments can be found at page 17, lines 19-27.

Applicant notes the Examiner's consideration of the information cited in the Information Disclosure Statement filed October 16, 2004, as acknowledged in the Office Action Summary.

Lack of Enablement Rejection

Claims 12 and 13 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabling because undue experimentation would be required to make and use the claimed subject matter. According to the Examiner, the specification "does not reasonably provide enablement for any polynucleotide that is 'capable' of hybridizing to SEQ ID NO: 3 under stringent conditions and that encodes a protein that is 'capable' of binding coelenterazine and oxygen and emitting light and that has a W or F at amino acid position 82 of SEQ ID NO: 4." The Examiner finds that undue experimentation would be required to practice "the invention commensurate in scope" with claims 12 and 13 as originally presented. The Examiner has cited and applied the Wand's factors to support her position. Applicant respectfully traverses this rejection because the Examiner has not presented any cogent reasoning to support her findings. In relying on the factors, the Examiner has made conclusionary statements without supporting evidence.

The Examiner asserts that the claims are "very broad because they recite any polynucleotide that is capable of hybridizing to SEQ ID NO: 3 under stringent conditions and that encodes a protein that is capable of binding coelenterazine and oxygen and emitting light and that has a W or F at amino acid position 82 of SEQ ID NO: 4." This is a conclusion. The phrase after "because" merely mirrors the claim language. No evidence or cogent reasoning has been presented as to why the claims are "very broad."

The Office Action describes the state of the art by discussing the Byran reference (U.S. Patent No. 5,876,995) and the difference between Byran's polynucleotide sequence and SEQ ID NO:3. The Examiner concludes that " Bryan's polynucleotide sequence has 99.5% sequence identity to Applicants' claimed sequence." This conclusion does not support why the state of the art would lead to a conclusion that undue experimentation would be required to practice the claimed subject matter.

As for the level of predictability in the art, the Examiner finds that "[b]ecause it is not known how to vary SEQ ID NO: 3 so that the encoded protein will have a W or F mutation at amino position 82, so that the encoded protein will be capable of binding coelenterazine and oxygen and emit light, and so that the variant of SEQ ID NO: 3, mutated at an unlimited number of positions (additions, deletions and substitutions) will hybridize under stringent conditions to SEQ ID NO: 3, the specification needs to have more detail as to how to make and use the invention." The finding is conclusory. It is not clear how this finding relates to predictability. Moreover, there is no explanation in the Office Action as to what guidance is lacking in the specification and why the guidance that is lacking would lead to undue experimentation.

The Examiner states that the specification does not define stringent conditions. Such conditions are disclosed at page 18, lines 9-18 of the specification, which states:

> Stringent conditions involve hybridizing at 68°C. in 5xSSC/5x Denhart's solution/1.0% SDS, and washing in 0.2xSSC/0.1% SDS at room temperature. Moderately stringent conditions include washing in 3xSSC at 42°C. The parameters of salt concentration and temperature be varied to achieve optimal level of identity between the primer and the target nucleic acid. Additional guidance regarding such conditions is readily available in the art, for example, Sambrook, Fischer and Maniatis, Molecular Cloning, a laboratory manual, (2nd ed.), Cold Spring Harbor Laboratory Press, New York, (1989) and F. M. Ausubel et al eds., Current Protocols in Molecular Biology, John Wiley and Sons (1994).

This portion of the specification provides guidance to a person having ordinary skill in the art regarding the stringent conditions required. The Office Action refers to page 18 of the specification as discussing "hybridization and washing conditions," but that "the washing conditions are more important than the hybridization conditions for determining what binds to a target DNA at the end of the experiment." There is no evidence presented by the Examiner to support this conclusion. The Office Action further asserts that

> Applicants use hybridization conditions that one of skill in the art would consider to be of high stringency. But, the room-temperature washing does not maintain stringent conditions. Thus, the DNA or RNA molecules that hybridize according to Applicants' protocol are not those that hybridize under stringent conditions. Because the prior art and the instant specification do not disclose any polynucleotide that is capable of hybridizing to SEQ ID NO: 3 under stringent conditions and that encodes a protein that is capable of binding coelenterazine and oxygen and emitting light and that has a W or F at amino acid position 82 of SEQ ID NO: 4, apart from SEQ ID NO: 3, it cannot be predicted that any other polynucleotide that is a variant of SEQ ID NO: 3 would encode a protein having all of the claimed functional properties.

No factual evidence has been presented to support a conclusion that one skilled in the art would consider Applicant's hybridization conditions to be of high stringency. No evidence has been

presented to support the room-temperature washing does not maintain stringent conditions. Both conclusory statements represent unsupported opinions of the Examiner. The Examiner's statement regarding predictability is also an opinion that lacks evidentiary support.

The Office Action concludes that the specification does not provide "any guidance for preparing any polynucleotide that is capable of hybridizing to SEQ ID NO: 3 under stringent conditions and that encodes a protein that is capable of binding coelenterazine and oxygen and emitting light and that has a W or F at amino acid position 82 of SEQ ID NO: 4, apart from SEQ ID NO: 3." Again, the Office Action is parroting the claim language and no evidence has been relied upon to show what criteria a person having ordinary skill in the art would have required.

As for the existence of working examples, such examples are not always required for enablement. The Office Action merely notes that such working examples are not present, but does not present any cogent reasoning as to why such examples would be necessary to practice the invention without undue experimentation.

The Office Action does provide the following explanation as to why experimentation would be necessary:

> To prove that polynucleotides exist that are capable of hybridizing to SEQ ID NO: 3 under stringent conditions and that encode proteins that are capable of binding coelenterazine and oxygen and emitting light and that have a W or F at amino acid position 82 of SEQ ID NO: 4, apart from the polynucleotide of SEQ ID NO: 3, many experiments would have to be conducted under a wide range of conditions. In these experiments, many different proteins encoded by many different variants of SEQ ID NO: 3 would have to be prepared and tested to see that each protein has the functional properties of an aqueorin, with W or F at position 82, and that each polynucleotide encoding each of these proteins hybridizes to SEQ ID NO: 3 under stringent conditions. Each variant of SEQ ID NO: 3, in addition to the required mutations at the codon of nucleic acid positions 347-348, would have to have a different number of nucleotides deleted and/or added and/or substituted. Many classes of variant polynucleotides would have to be prepared, those with nucleotides: deleted and added, deleted and substituted, added and substituted, and deleted, added and substituted. For each class, a large number of sets of

polynucleotides would have to be prepared, each set having a different of nucleotides changed rom the original SEQ ID NO: 3. For each set, a large number of subsets would have to be prepared, each subset having a different permutation of nucleotide positions changed. For each subset, a large number of members would have to be prepared, each member in each subset having a different group of nucleotides at the altered positions. For all polynucleotides that hybridize under stringent conditions to SEQ ID NO: 3, all the encoded proteins would have to be shown to have the functional properties of an aequorin.

These types of experiments and data are missing from the specification. A great deal of guidance is needed to establish that a genus of polynucleotides that are capable of hybridizing to SEQ ID NO: 3 under stringent conditions and that encode proteins that are capable of binding coelenterazine and oxygen and emitting light and that have a W or F at amino acid position 82 of SEQ ID NO: 4 can be made, apart from SEQ ID NO: 3, because this genus is claimed, and only one species is disclosed. Even if one additional species could be made and identified by random, trial-and-error experimentation, without a very large amount of data, such a result would not allow one of skill in the art to expect that a second undisclosed species exists.

The statements above represent the Examiner's opinion as to what experiments would be required. There is no evidence presented to support what a person having ordinary skill in the art would require with respect to experimentation and why. Moreover, it is well established that patent specifications were not intended to be blueprints or production documents which provide every detail for the practice of the invention. This is so because the specification speaks to one skilled in the art. *DeGeorge V. Bernier*, 226 U.S.P.Q. 258,262 (Fed. Cir. 1985). Thus, the Examiner's perception of the quantity of experimentation necessary is not persuasive that the claims fail for enablement.

It appears form the rejection that the Examiner has trouble with the word "capable" in the original claims. In order to expedite prosecution, Applicant has amended claims 12 and 13 to recite an isolated nucleic acid having at least 95% similarity to SEQ ID NO: 3 under stringent conditions and encoding a protein which is capable of binding coelenterazine and molecular oxygen and emitting light. It is believed that by this amendment to the claims, that the objected to language is overcome.

For all of the foregoing reasons, it is respectfully requested that the rejection of claims 12 and 13 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Indefiniteness Rejection

Claims 12 and 13 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner finds "stringent conditions" indefinite because "the specification does not define or disclose stringent conditions, nor does it disclose any polynucleotides that bind under stringent conditions to SEQ ID NO: 3, regardless of what proteins they encode." Applicant respectfully traverses this rejection.

The legal standard for indefiniteness under the second paragraph of 35 U.S.C. § 112 is whether a claim reasonably apprises those of skill in the art of its scope. *See Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir.), *cert. denied sub nom., Genetics Inst., Inc. v. Amgen, Inc.*, 112 S.Ct. 169 (1991). The definiteness of the language employed must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and the application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *See In re Angstadt,* 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976). The Examiner has not presented such an analysis, but has suggested that the "claims may be amended to recited polynucleotides encoding a protein that is a variant of SEQ ID NO:4 in which position 82 is W of F."

As discussed *supra*, with respect to the enablement rejection, the "stringent conditions" are set forth at page 18, lines 9-17 of the specification. A person skilled in the art reading the

specification would be reasonably apprised of the scope of the invention from this disclosure. The Examiner has not provided any analysis to show how and why the aforementioned disclosure would not apprise such a person of the scope of the claimed invention.

Further, if the basis for indefiniteness is breadth of the term "stringent conditions," it is well settled that breadth is not indefiniteness. *In re Gardner*, 427 F.2d 786, 788, 166 USPQ 138, 140 (CCPA 1970); *In re Conley*, 490 F.2d 972, 975, 180 USPQ 454, 456 (CCPA 1974).

For all of the foregoing reasons, it is respectfully requested that the rejection under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

Conclusion

For the foregoing reasons, it is submitted that the claims 12 are patentable over the first and second paragraphs of 35 U.S.C. § 112. Accordingly, favorable reconsideration of the claims is requested in light of the preceding amendments and remarks. Allowance of the claims is courteously solicited.

If there are any outstanding issues that might be resolved by an interview or by an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due under 37 C.F.R. § 1.17 and due in

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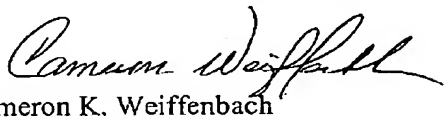
connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT, WILL & EMERY



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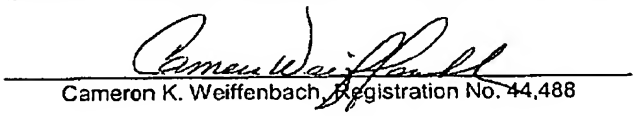

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